

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 2000 list were published in the Federal Register in February 2000.

### Supplemental Approvals

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**NADA Number: 065-480**

**This supplemental application provides for a revised withdrawal period (from five to zero days) in swine.**

Trade Name: Chlortetracycline Soluble Powder  
Ingredients: Chlortetracycline hydrochloride  
Sponsor: Pennfield Oil Company  
Approval Date: December 22, 1999  
Status: Over-the-counter  
Route: Oral  
Species: Swine and calves  
Drug Form: Powder  
Concentration: 64 grams chlortetracycline hydrochloride per pound  
Indications: For the treatment and control of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp., *Klebsiella* spp. and *Hemophilus* in swine and calves (excluding veal calves).  
Tolerance: 21CFR 556.150: The tolerances established for the sum of residues of tetracycline including chlortetracycline, oxytetracycline, and tetracycline are as follows: 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in kidney and fat. The ADI for total residues of tetracycline including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.  
Withdrawal: Zero day

21CFR 520.445b

**NADA Number: 140-992**

**This supplemental application provides for the use of a higher dose ear implant for steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency .**

Trade Name: Revalor<sup>®</sup>-200  
Ingredients: Trenbolone acetate, estradiol  
Sponsor: Hoechst Roussel Vet  
Approval Date: November 29, 1999  
Status: Over-the-counter  
Route: Subcutaneous ear implant  
Species: Cattle, steers fed in confinement  
Drug Form: Implant  
Concentration: 200 mg trenbolone acetate and 20 mg estradiol per implant  
Indications: For increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter.  
Tolerance: 21CFR 556.240: Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentration of estradiol naturally present in untreated animals; in the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion in muscle, 480 parts per trillion in fat, 360 parts per trillion in kidney, and 240 parts per trillion in liver.  
21CFR 556.739: Trenbolone: A tolerance for total residues in uncooked edible tissues of cattle is not needed. An ADI (acceptable daily intake) of 0.4 micrograms per kilogram of body weight per day has been established.  
Withdrawal: Zero days  
Exclusivity: 3 years

21CFR 522.2477

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### Change of Sponsor

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**NADA Number: 113-645**

From: Bayer Corp., Agriculture Division, Animal Health  
To: Schering-Plough Animal Health Corp.  
1095 Morris Ave.  
Union , NJ 07083  
Drug labeler code: 000061

<b>NADA Numbers:</b>	<b>006-019</b>	<b>006-081</b>	<b>006-776</b>
	<b>006-860</b>	<b>006-891</b>	<b>008-902</b>
	<b>100-094</b>	<b>100-175</b>	<b>100-176</b>
	<b>130-435</b>	<b>200-106</b>	<b>200-189</b>
	<b>200-274</b>		

From: I.D. Russell Co., Laboratories  
To: Alpha Inc.  
One Executive Drive  
P.O. Box 1399  
Fort Lee, NJ 07024  
Drug labeler code: 046573

### Suitability Petition Action

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Number:	00P-0444/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, spectinomycin dihydrochloride pentahydrate, which differs from the pioneer product, spectinomycin sulfate tetrahydrate (Adspec <sup>TM</sup> Sterile Solution), Pharmacia & Upjohn Co., NADA 141-077, by the following characteristic: The generic product differs in the salt form of the active drug substance.
Action:	Filed on February 4, 2000.
Number:	00P-0596/CP1
Sponsor:	Phoenix Scientific, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, phenylbutazone (Phoenix Scientific, Inc.), NADA 091-818, by the following characteristic: The generic product will consist of a different physical form, powder, whereas the pioneer approved product is a tablet.
Action:	Filed on February 14, 2000.